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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,678	12/07/2001	Glenn J. Gormley	19109DE	1340

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EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 07/16/2002 4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/010,678	Applicant(s) GORMLEY ET AL.	
	Examiner Vickie Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 28-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 28-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. It is noted that section heading TITLE OF THE INVENTION including the text has been appeared twice in page 1 and page 19. It is proper to delete the duplicated section heading TITLE OF THE INVENTION including the text in page 19. Clarification is required.

Arrangement of the Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) BRIEF SUMMARY OF THE INVENTION.
(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Status of Application

2. Preliminary amendment filed on December 07, 2001 is properly entered.

3. Claims 1-27 are cancelled. New claims 28-37 are presented for the examination.

Information Disclosure Statement

4. The information disclosure statement filed March 12, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. However, it has been placed in the application file, even though not all the references referred to therein have been considered. Since the patented references can be obtainable easily by this examiner, only those patented references have been reviewed, and initialed properly at PTO-1449. The copy of PTO-1449 that is initialed(i.e. pages 1 & 2), will be attached with this instant office action. Pages 3 &4 are not attached as they were not reviewed.

Claim Objections

5. Claim 37 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 37 recites "the transdermal skin patch composition according to claim 35". However, the claim 35 is a method claim. It appears that applicants intended claim 37 to depend from claim 36. Clarification is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 31 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 31 is indefinite since it is not clear if the halogen substituents are restricted to those set forth in the parenthetical expression. An amendment to the claim 31 reciting ".... 1 or more halogen substituents selected from the group consisting of CL, F or Br" would obviate this rejection.

b. Claim 37 recites the limitation " the 5 alpha-reductase 2 inhibitor" in line 2. There is no antecedent basis for this limitation in the claim 35. An amendment to claim 37 changing the claim dependency to claim 36 would obviate this rejection.

Claim Rejections - 35 USC § 102

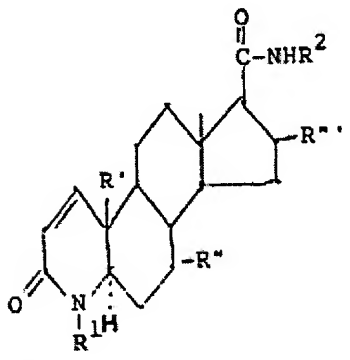
8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 28-29 and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Rasmusson et al (EP 0285382 A2).

Rasmusson teaches a treatment of androgenic alopecia using 5 alpha reductase inhibitors(e.g.17-beta-N-monosubstituted-carbamoyl-4-aza-5alpha-androst-1-ene-3-ones). Rasmusson also teaches the limitations recited in claims 29 and 34

(i.e. a treatment of male pattern baldness) and the species required by claim 33 (i.e. 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one) as a preferred species, see abstract; page 2, line 47; examples 6-12 and claims 1-4 and 6-8. It also teaches the patented compounds having the formula found in patented claim 1 as follows:



(wherein:
R^1 is hydrogen, methyl or ethyl;
R^2 is a branched chain alkyl of from 3-12 carbon atoms;
R' is hydrogen or methyl;
R'' is hydrogen or β-methyl;
R''' is hydrogen, α-methyl or β-methyl) for the manufacture of a medicament useful for treating androgenic alopecia.

The formulas I and II required by the instant claims 31 and 32 are encompassed by the patented formula shown above(supra). Even though the instant claims use the term "5alpha-reductase 2 inhibitor" whereas Rasmusson(EP'382) uses the term "5alpha-reductase inhibitor", they are considered to be the same or inherently same since they have same structure and utility. All the critical elements required by the instant claims are taught by the cited reference. Thus, all the claimed subject matter is rejected over the prior art of the record.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 30 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmusson et al (EP 0285382 A2) in view of Goldman(US 5,407,944).

Rasmusson et al's teaching is mentioned in 102 rejection. For instance, the patented claim 8 teaches various alternative topical formulations including solution, cream, ointment, gel, shampoo or aerosol. Rasmusson teaches most elements required by the instant claims 30 and 35-37 except a topical application being formulated in the form of a transdermal skin patch.

However, it would be obvious to one of ordinary skill in the art to make a transdermal skin patch comprising a 5α-reductase 2 inhibitor to treat androgenic alopecia(e.g. male pattern baldness) when Rasmusson's reference is modified with Goldman because Goldman suggests that a pharmaceutical preparation could be made in the form of a topical transdermal skin patch comprising a composition containing 5α-reductase 2 inhibitor (e.g. finasteride®), see column 6, lines 10 and 20, especially line 28. Goldman teaches a method for promoting hair growth using a vasodilator in combination with estradiol and/or a 5alpha-reducatse inhibitor. Since the techniques for formulating a transdermal patch is well within the skilled level of the artisan having ordinary skill in the art, one would have had the reasonable expectation of success for treating adrogenic alopecia by utilizing a skin patch formulation of 5alpha-reductase 2

inhibitor as an active component taught by Rasmusson. Thus, one would have been motivated to modify Rasmusson's teaching to include a transdermal skin patch to extend the applicability and acceptance by the patient who prefers a patch application to fit their needs, wherein the increased compliance would enhance the therapeutic efficacy and achieve cost-effective treatment via short duration of therapy and because this is seen as an alternative means to deliver medications. It is noted that finasteride® is 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

Double Patenting

12. Claims 28-29 and 31-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,547,957. The instant claims requires an effective amount of a 5alpha-reductase 2 inhibitor to treat male pattern baldness whereas US'957 teaches a therapeutically effective dosage amount from 0.05 to 3.0mgs/day for the same treatment. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 (US patent '957) is directed to a method of treating male pattern baldness comprising 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one wherein male pattern baldness is androgenic alopecia, and 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one is an inhibitor of 5α-reductase 2 , admitted by both patent

and instant application, see US'957, column 1, lines 14-15 and lines 50-55; and see instant claims 2 and 33. In fact, one would have easily discovered the effective dosage required by the instant claims for treating androgenic alopecia is about 0.01 to 3.0gms/day when the claims are read in light of specification(see page 3, line 9). It would have been obvious to one of ordinary skill in the art to expect the same result from the method required by both application and patented composition.

13. Claims 28 and 31-33 are also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No.5,760,046. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 (US patent '406) is directed to a method of treating female pattern baldness whereas the instant claims require the androgenic alopecia. However, the female pattern baldness is considered to be a manifestation of androgenic alopecia and encompassed by the term androgenic alopecia when this patented claim is read in light of specification(see US'406, column 1, lines 18-19 and lines 54-63). Thus, it would have been obvious to one of ordinary skill in the art to substitute female pattern baldness to androgenic alopecia as suggested in US'406 patent. One would have been motivated to substitute androgenic alopecia to female pattern baldness and expected successful treatment from this substitution. Specific dosage(i.e. 0.05 to 3.0mgs/day) is considered to be a therapeutically effective amount as mentioned earlier(supra) for treating androgenic alopecia.

Conclusion

14. All the pending claims 28-37 are rejected.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
July 12, 2002
Art unit 1614